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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,123	04/02/2002	Mary Collins	22058-514NATL	5639

7590 06/03/2005

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EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,123

Applicant(s)

COLLINS ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 28, 48-53, 55-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23, 48-53 and 55 is/are allowed.
- 6) ☒ Claim(s) 28, 56 and 58-62 is/are rejected.
- 7) ☒ Claim(s) 57 and 64-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2005 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 27 April 2005 has been entered in full. Claims 1-22, 24-27, 29-47, 54 and 63 were cancelled. Claims 23, 28 and 48-53, 55-62, 64-67 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 23, 28, 48-67 under 35 USC 112, first paragraph, scope of enablement, as set forth at pages 3-4 of the previous Office Action (27 October 2004), is *withdrawn* in view of the amendment (27 April 2005).

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The rejection to claims 23, 28 and 48-67 under 35 USC 112, first paragraph, written description, new matter, as set forth at pages 5-6 of the previous Office Action (27 October 2004), is *withdrawn* in view of the amendment (27 April 2005).

The rejection to claims 23, 28 and 48-67 under 35 USC 112, first paragraph, written description, as set forth at pages 6-8 of the previous Office Action (27 October 2004), is *withdrawn* in view of the amendment (27 April 2005).

The rejection to claims 23 and 28 under 35 USC 112, second paragraph, as set forth at page 8 of the previous Office Action (27 October 2004), is *withdrawn* in view of the amendment (27 April 2005).

The objection to claim 23, as set forth at page 9 of the previous Office Action (27 October 2004), is *withdrawn* in view of the amendment (27 April 2005).

Claim Rejections - 35 USC § 112, First paragraph, Scope of Enablement

Claims 28 and 56, 58-62 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

"a method of treating an IL-13-related condition in a mammalian subject.....wherein said IL-13 related condition is **allergen-induced airway hyper responsiveness (AHR) or asthma**"

does not reasonably provide enablement for:

"a method of treating an IL-13-related condition in a mammalian subject.....wherein said IL-13 related condition is an **allergic condition or atopy**".

The basis for this rejection is set forth at pages 4-5 of the previous Office Action (27 October 2004).

Applicant argues that the Office has failed to provide adequate support for doubting the inaccuracy of the present disclosure. Applicant argues that the burden is on the Examiner to provide evidence or reasoning of the contrary. Applicant cites the Guidelines for the Examination of Patent Applications under 35 USC 112, first paragraph. Applicant asserts that they have provided ample and sufficient enabling teachings such that one skilled in the art would be able to practice the claimed invention in the absence of undue experimentation. Applicant cites pages from the instant specification. Applicant maintains that the Office states that experimental data must be presented for each indication claimed in spite of Applicant's teachings that the claimed method is useful in a murine model of airway hyper responsiveness (AHR). Applicant cites the MPEP. Applicant argues that the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue experimentation.

Applicant's arguments have been fully considered but are not deemed persuasive. The Examiner stated in the previous Office Action that the instant specification teaches the reversal of AHR in mice upon the administration of IL-13bc (SEQ ID NO:3, SEQ ID NO:4)(page 28, line 20-page 29, line 11). The Examiner conceded in the previous Office Action and stated that the AHR murine model *may* encompass asthma. However, the terms "allergic condition" and "atopy" apply to any type of allergic condition or reaction. The Examiner provided a definition of atopy, which

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was defined as an allergic reaction with strong family tendencies. The scope of the instant claims far exceeds the scope of the enabling disclosure. The instant claims encompass allergies to various foods, medications and diverse conditions such as hives, hay fever, and eczema. Allergic conditions can encompass antibodies, which react with one's own antigens and includes diseases such as rheumatoid arthritis, insulin resistant diabetes mellitus, myasthenia gravis, Grave's disease, Lupus, etc. The instant specification establishes no connection between any of these diverse conditions and the instant invention. Applicant failed to provide references, which teach that the instant invention can be used to treat any allergic condition/reaction or that the AHR murine model is applicable to any allergic condition/reaction. Furthermore, the instant specification teaches that airway hyper responsiveness (AHR) is not dependent upon IgE production. One of the most powerful effector mechanisms of the immune system is the reaction initiated by IgE dependent stimulation of mast cells. Thus, it is not clear that the instant invention would work for any and all types of allergic conditions/reactions. The Examiner agrees with Applicant, that the specification need not contain an example, however, lacking a working example is a factor to be considered in a case involving unpredictability and undue experimentation.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

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Claim Objections

Claim 57, 64-67 are objected to for depending from a rejected claim but would allowable if rewritten in an independent form.

Conclusion

Claims 23, 48-53 and 55 are allowable.

Claims 57, 64-67 are objected to.


Claims 28, 56, 58-62 are rejected.

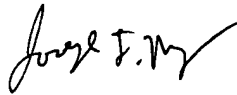
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RMD
5/31/05


JOSEPH MURPHY
PATENT EXAMINER